REMARKS

Claims 1-3, 5-12, 15-21, and 23-30, 33-36 are pending.

Claims 13-14 and 31-32 are withdrawn.

As required under 35 U.S.C. 121 a provisional election is hereby made without traverse to prosecute claims 11 and 29.

Claims 4 and 22 are canceled.

Claim Rejections - 35 USC § 112

Claims 4, 15, 22 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

However, the first paragraph on page 4 appears to reject claims as lacking enablement with respect to the preparation of the claimed, hydrolyzed di-and tri-block copolymers.

Claims 4 and 22 are canceled.

Applicants respectfully points out that this limitation is enabled by the methods described on pages 10-16 to a person of ordinary skilled in the art. For example, page 12 of the specification provides that a carboxylated poly(lactic acid) can be made according to equation (II) by reacting lactide with HO–R–COOH when R is a polymer chain. This equation generates a carboxylated block copolymer. Similarly, the specification provides that a hydroxylated poly(lactic acid) can be made according to equation (I) and formula (III) on page 10 and page 14, respectively. Formula (III) describes diblock copolymer, DLPLA-PEG which can be made according to a method similar to equations (I) and (II), where one reactant is DLPLA and other reactant is PEG. Further, formulae (IV) and (V) teach triblock copolymer of DLPLA-PEG-DLPLA and PEG-DLPLA-PEG, which can be made according to a method similar to equations (I) and (II), where one reactant is DLPLA and other reactant is PEG. Therefore, claim 15 and 33 are enabled to a person of ordinary skilled in the art.

Claim Rejections - 35 USC § 102

Claims 1-12, 15-21, 23-30 and 34-36 are rejected under 35 U.S.C. 102 (b) as being anticipated by Yang et al. (US 6,258,121 B1).

Claim 1 defines a medical article comprising an implantable substrate having a coating. The coating includes a derivative of carboxylated or hydrolyzed poly(lactic acid), or a block-copolymer having at least one moiety comprising a derivative of carboxylated or hydrolyzed poly(lactic acid). The hydrolyzed poly(lactic acid) has an average molecular weight between about 1,000 and about 20,000 Daltons. A person of ordinary skill in the art would recognize that using the hydrolyzed or carboxylated poly(lactic acid) increases the rate of degradation of the polymer in the coating, which leads the increased rate of release of the drug from the coating. By selecting specific average molecular weight of hydrolyzed poly(lactic acid) to form a coating, the current invention provides smooth release of drug through degradation of the polymer. Therefore, use of hydrolyzed or carboxylated poly(lactic acid) and average molecular weight of hydrolyzed poly(lactic acid) are important features of a medical article of claim 1.

Yang discloses a stent having a polymeric coating for controllably releasing an active agent. The coating includes a first PLA-PEO co-polymer which releases a biological agent faster while a second PLA-PCL co-polymer which releases a biological agent slower. The biologically active agent dispersed in the coating (Abstract, col. 4, line 4-22).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Yang does not describe a medical article having a coating of a derivative of carboxylated or hydrolyzed poly(lactic acid) as required by claim 1. Yang clearly fails to describe the hydrolyzed poly(lactic acid) having an average molecular weight between about 1,000 and about 20,000 Daltons as

defined by claim 1. Therefore, Yang cannot anticipate claim 1 of the present invention. Accordingly, claim 1 is patentably allowable over Yang. Claims 2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 15, 16, 17 and 18 depend from claim 1 and are patentably allowable over Yang for at least the same reason.

Claim 19 is directed to a method for fabricating a medical article. The method includes depositing a coating on an implantable substrate. The coating includes a polymer comprising a derivative of carboxylated or hydrolyzed poly(lactic acid), or a block-copolymer having at least one moiety comprising a derivative of carboxylated or hydrolyzed poly(lactic acid). The hydrolyzed poly(lactic acid) having an average molecular weight between about 1,000 and about 20,000 Daltons.

As discussed above, Yang does not describe a method of depositing a coating of a derivative of carboxylated or hydrolyzed poly(lactic acid) polymer as defined in claim 19. Yang also fails to describe the hydrolyzed poly(lactic acid) having an average molecular weight between about 1,000 and about 20,000 Daltons as required by claim 19. Therefore, Yang cannot anticipate claim 19 of the present invention. Accordingly, claim 19 is patentably allowable over Yang. Claims 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 34, 35 and 36 depend from claim 19 and are patentably allowable over Yang for at least the same reason.

Claims 1-9, 15-27 and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwarz (US 2003/0203000 Al),

Claim 1 is directed to a medical article comprising an implantable substrate having a coating. The coating includes a derivative of carboxylated or hydrolyzed poly(lactic acid), or a block-copolymer having at least one moiety comprising a derivative of carboxylated or hydrolyzed poly(lactic acid). The hydrolyzed poly(lactic acid) has an average molecular weight

between about 1,000 and about 20,000 Daltons. Therefore, claim 1 requires a medical article having a coating of a derivative of carboxylated or hydrolyzed poly(lactic acid), or a block-copolymer having at least one moiety derived from poly(lactic acid) and an average molecular weight of hydrolyzed poly(lactic acid) specifically between about 1,000 and about 20,000 Daltons.

Schwarz discloses a method of modulating a rate of release of therapeutic agent from a medical device having therapeutic-agent-loaded polymeric carriers. The polymeric carrier can comprise a blend of polymers such as PEO-PLA copolymer, PCL, PHB and polyhydrovalerate [0009], [0016]-[0018], [0028], [0031]-[0032].

However, Schwarz does not describe a medical article having a coating of carboxylated poly(lactic acid) as defined in claim 1. For example, Schwarz does not describe a derivative of carboxylated or hydrolyzed poly(lactic acid) or a block-copolymer having at least one moiety comprising a derivative of carboxylated or hydrolyzed poly(lactic acid). Further, Schwarz does not to describe the hydrolyzed poly(lactic acid) specifically having an average molecular weight between about 1,000 and about 20,000 Daltons as set forth in claim 1. Therefore, Schwarz cannot anticipate claim 1 of the present invention. Accordingly, claim 1 is patentably allowable over Schwarz. Claims 2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 15, 16, 17 and 18 depend from claim 1 and are patentably allowable over Yang for at least the same reason.

Claim 19 is drawn to a method for fabricating a medical article having a coating. The coating includes a polymer of carboxylated or hydrolyzed poly(lactic acid), or a block-copolymer having at least one moiety derived from poly(lactic acid). The hydrolyzed poly(lactic acid) having an average molecular weight between about 1,000 and about 20,000 Daltons.

Schwarz describes a method of modulating a rate of release of therapeutic agent from a medical device having therapeutic-agent-loaded polymeric carriers. As discussed above,

Schwarz does not to describe the hydrolyzed poly(lactic acid) having an average molecular weight between about 1,000 and about 20,000 Daltons as required by claim 19. Further, Schwarz fails to describe a method of fabricating a medical article having the coating of carboxylated or hydrolyzed poly(lactic acid) or a block copolymer having at least one moiety comprising a derivative of carboxylated or hydrolyzed poly(lactic acid) as set forth in claim 19. Therefore, Schwarz cannot anticipate claim 19 of the present invention. Accordingly, claim 19 is patentably allowable over Schwarz. Claims 20, 21, 23, 24, 25, 26, 27, 34, 35 and 36 depend from claim 19 and are patentably allowable over Schwarz for at least the same reason.

Claim Rejections - 35 USC § 103

Claims 1-12, 15-30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (US 6,258,121B1) in view of Okada (US 6,113,943).

As discussed above, claim 1 defines a medical article having a coating. The coating includes carboxylated or hydrolyzed poly(lactic acid), or a block-copolymer having at least one moiety comprising a derivative of carboxylated or hydrolyzed poly(lactic acid). The hydrolyzed poly(lactic acid) has an average molecular weight between about 1,000 and about 20,000 Daltons.

Yang describes a stent having a polymeric coating for controllably releasing an active agent. The coating includes a first PLA-PEO co-polymer which releases a biological agent faster while a second PLA-PCL co-polymer which releases a biological agent slower. The biologically active agent dispersed in the coating (Abstract, col. 4, line 4-22).

As Examiner correctly notes, Yang does not teach a hydrolyzing treatment for polymers used in the coating as defined in claim 1. Further, there is no teaching in Yang for one of ordinary skilled in the art to use carboxylated or hydrolyzed poly(lactic acid) polymers for medical devices. Finally, there is no suggestion in Yang to use hydrolyzed poly(lactic acid)

having specific average molecular weight between about 1,000 and about 20,000 Daltons for stents as required by claim 1.

Okada describes a sustained-release preparation of hydrolyzed polymer of lactic acid having average molecular weight of 25,000 to 60,000 Daltons for réleasing physiologically active substance. Okada does not teach a medical article having a coating of carboxylated poly(lactic acid) polymers as set forth in claim 1. Further, Okada does not teach or even remotely suggest using hydrolyzed poly(lactic acid) having specific average molecular weight between about 1,000 and about 20,000 Daltons for medical device as required by claim 1. One of ordinary skill in the art would recognize that polymers having different molecular weights will exhibit different chemical, biological and physical properties. For example, polymers having different molecular weights can have different solubility. Polymers having different molecular weights can have different release mechanism and different release rates. In addition, carboxylated or hydrolyzed groups are highly hydrophilic groups and will impart hydrophilic properties to a coating including a polymer having either of these groups, e.g. increased moisture or water uptake as to increase release rate of a therapeutic agent.

Therefore, Okada does not cure the deficiency of Yang. There is no motivation for one of ordinary skill in the art to combine a method of Yang with Okada for medical article as defined in claim 1. Yang and Okada, individually or combined do not teach a medical article as defined in claim 1. Accordingly, claim 1 is patentably allowable over Yang and Okada, individually or combined. Claims 2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 15, 16, 17 and 18 depend from claim 1 and are patentably allowable over Yang and Okada, individually or combined, for at least the same reason.

Claim 19 defines a method for fabricating a medical article having a coating. The coating includes a polymer comprising a derivative of carboxylated or hydrolyzed poly(lactic

acid), or a block-copolymer having at least one moiety comprising a derivative of carboxylated or hydrolyzed poly(lactic acid). The hydrolyzed poly(lactic acid) having an average molecular weight between about 1,000 and about 20,000 Daltons. As seen from the discussion of claim 1, Yang does not teach a hydrolyzing treatment for polymers used in the coating as defined in claim 19. Further, Yang fails to teach carboxylated or hydrolyzed poly(lactic acid) polymers for medical devices. Finally, Yang does not suggest or teach to use hydrolyzed poly(lactic acid) having average molecular weight between about 1,000 and about 20,000 Daltons for medical devices as set forth claim 19.

Okada does not teach or even remotely suggest a method for fabricating medical article using hydrolyzed poly(lactic acid) having average molecular weight between about 1,000 and about 20,000 Daltons for medical device as required by claim 19. Further, Okada fails to teach a method for fabricating a medical device having a coating of carboxylated poly(lactic acid) polymers as defined in claim 19.

Therefore, Okada does not cure the deficiency of Yang. There is no motivation for one of ordinary skill in the art to combine the teaching of Yang with Okada for a method of fabricating medical article as defined in claim 19. Yang and Okada, individually or combined do not teach a method of fabricating a medical article as defined in claim 19. Accordingly, claim 19 is patentably allowable over Yang and Okada, individually or combined. Claims 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 34, 35 and 36 depend from claim 19 and are patentably allowable over Yang for at least the same reason.

Double Patenting

Claims 1-9, 11, 15, 18, 19-21, 23-27, 29 and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being. unpatentable over claims 1-19 of U.S. Patent 7,169,404.

Applicants submit a terminal disclaimer over U.S. Patent 7,169,404. Applicants believe this would render the rejection moot.

Claims 1-12,15-21,23-30 and 34-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 17, 24-26, 37, 68-78 of copending Application No. 10/925257.

Applicants submit a terminal disclaimer over copending Application No. 10/925257. Applicants believe this would render the rejection moot.

CONCLUSION

In view of the above remarks, Applicants request withdrawal of the rejection. Since all claims are in a condition for allowance, please issue a Notice of Allowability. Should the Examiner have any questions regarding this response or comments that would move the case towards allowance, the Examiner is invited to call the undersigned attorney of record.

Respectfully submitted,

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